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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,785	09/23/2003	Troy M. Just		4104
31083	7590	01/24/2006		
THOMTE, MAZOUR & NIEBERGALL, L.L.C. 2120 S. 72ND STREET, SUITE 1111 OMAHA, NE 68124			EXAMINER HAND, MELANIE JO	
			ART UNIT	PAPER NUMBER
			3761	

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/668,785		JUST, TROY M.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Melanie J. Hand		3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. ____.  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>11/19/03</u> .  | 6) <input type="checkbox"/> Other: ____.                                    |

## DETAILED ACTION

### *Information Disclosure Statement*

The information disclosure statement (IDS) submitted on November 19, 2003 was filed after the mailing date of the Application on September 23, 2003. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 and 8-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Ferrer et al (U.S. Patent No. 6,364,854).

With respect to **Claim 1,8,9,13**: Ferrer teaches vaginal medication applicator 10 comprising main tubular body 20, plunger 30, piston 40 and cap 50. Main body 20 has a closed dispensing end 21 with a plurality of openings 26 and an open grasping end 22. Piston 40 is slidably mounted on a rod within said main body 20 and is therefore capable of being selectively positioned. Piston 40 fits snugly within section 23 of the main applicator body and provides a closure to the compartment wherein medication is stored and has sealing flange 43 disposed on its outer surface that engages with the inner surface of section 23 of body 20. Central section 41

of piston 40 has a longitudinal orifice 45 running therethrough. As can best be seen in Fig. 5, said orifice 45 terminates on two ends, both of which are located between first and second ends of piston 40. Plunger 30 and piston 40 are configured so as to fit together to form the impeller system for dispensing the medication outward from said body 20. Plunger 30 has inner end 31 that is always housed inside body 20 and is slidably engageable with piston 40. Piston 40 has an outer diameter that is larger than body 20 due to the presence of flange 43, therefore said piston is in a compressed state whenever it is disposed within body 20. Due to this compression, upon application of force to piston 40 by plunger 30, piston 40 is pushed along body 20 toward dispensing end 21 while being longitudinally stretched. Pairs of elements 46-35 and 47-34 act to retain the piston in an engaged position at one end of the plunger, allowing discharge of medication and preventing accidental disassembly of the plunger-piston system while the applicator is being used. (Col. 2, lines 51-65, Col. 4, lines 14-17, 20-27, 36-40, 49-53, 57-67, Col. 5, lines 22, 23, 28-35, Col. 7, lines 11,12)

With respect to **Claims 2,10**: Ferrer teaches that piston 40 fits snugly within portion 23 of body 20 and is thus receivable in openings 26. (Col. 4, lines 19,20)

With respect to **Claims 3,11**: Ferrer teaches that piston 40 is comprised of flexible material, therefore if manual force is applied said piston will deform and will be rendered unusable. (Col. 2, lines 60,61)

With respect to **Claims 4,12**: Ferrer teaches that dispensing end 21 is rounded. (Col. 3, line 12)

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With respect to **Claim 5,14**: Ferrer teaches projections 63 on the inner surface of cap 50 whose size, shape and number correspond to the size, shape and number of openings 26 such that projections 63 fit perfectly into these openings and provide a tight seal. (Col. 5, lines 28-35)

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6, 7, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferrer et al ('854) in view of Reinhard et al (U.S. Patent No. 6,280,418).

With respect to **Claims 6,7,15,16**: Ferrer does not teach that cap 50 is threadably fitted onto dispensing end 21. Reinhard teaches a container with a plunger 7 and rod 9 having threaded piece 5 that accommodates a sealing cap for sealing connector cone 3 which forms a neck opening to the syringe barrel. ('418, Fig. 1a) ('418, Col. 5, lines 29-31, 37-40) Reinhard teaches that this cap 6 provides a seal with the exterior lateral face of connector cone 3 ('418, Col. 5,

lines 46-50), therefore the threadably fitting cap taught by Reinhard is simply an alternate method for providing a tight seal preventing contamination or loss of medication to the snap fitting cap taught by Ferrer. In the instant case substitution of equivalent methods requires no express motivation, as long as the prior art recognizes equivalency, *In re Fount* 213 USPQ 532 (CCPA 1982); *In re Siebentritt* 152 USPQ 618 (CCPA 1967); *Graver Tank & Mfg. Co. Inc. v. Linde Air Products Co.* 85 USPQ 328 (USSC 1950).

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Melanie J Hand  
Examiner  
Art Unit 3761

MJH

TATYANA ZALUKAEVA  
SUPERVISORY PRIMARY EXAMINER

